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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ESPERION THERAPEUTICS, INC.,)	
)	
)	
)	
Plaintiff,)	
)	
v.)	C.A. No. 24-_____
)	
AUROBINDO PHARMA LIMITED,)	
APITORIA PHARMA PRIVATE)	
LIMITED,)	
)	
Defendants.)	
)	

COMPLAINT FOR PATENT INFRINGEMENT

1. This is an action for patent infringement by Esperion Therapeutics, Inc. (“Esperion”) under the patent laws of the United States, Title 35 U.S.C. § 100 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02, against Defendants Aurobindo Pharma Limited and Apitoria Pharma Private Limited (collectively, “Aurobindo”). This action arises out of Aurobindo’s submission of Abbreviated New Drug Application (“ANDA”) No. 219349 to the U.S. Food and Drug Administration (“FDA”) seeking approval to manufacture and sell a generic version of NEXLETOL[®] prior to the expiration of U.S. Patent Nos. 11,760,714 and 11,613,511 (collectively, the “Asserted Patents”).

PARTIES

2. Plaintiff Esperion is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 3891 Ranchero Drive, Suite 150 Ann Arbor, MI 48108.

3. Upon information and belief, Defendant Aurobindo Pharma Limited (“Aurobindo Pharma”) is a corporation organized and existing under the laws of India, having a principal place of business at Galaxy, Floors: 22-24, Plot No. 1, Survey No. 83/1, Hyderabad Knowledge City, Raidurg Panmaktha, Ranga Reddy District, Hyderabad, Telangana, 500032, India.

4. Upon information and belief, Aurobindo Pharma is a pharmaceutical company that engages in the manufacture, marketing, or sale of pharmaceutical products, including generic drug products manufactured and sold pursuant to approved ANDAs.

5. Upon information and belief, Aurobindo Pharma directly or through its affiliates develops, markets, and sells drug products throughout the United States, including in the state of New Jersey.

6. Upon information and belief, Apitoria Pharma Private Limited (“Apitoria”), formerly known as Auro Pharma India Private Limited, is a corporation organized and existing under the laws of India, having a principal place of business at Galaxy, Floors: 22-24, Plot No. 1, Survey No. 83/1, Hyderabad Knowledge City, Panmaktha, Rai Durg, Hyderabad, 500032, India.

7. Upon information and belief, Apitoria is a pharmaceutical company that engages in the manufacture, marketing, or sale of pharmaceutical products, including generic drug products manufactured and sold pursuant to approved ANDAs.

8. Upon information and belief, Apitoria directly or through its affiliates markets and sells drug products throughout the United States, including in the state of New Jersey.

9. Upon information and belief, Apitoria is the holder of FDA Drug Master File No. 38811 for Bempedoic Acid.

10. Upon information and belief, Apitoria is a wholly-owned subsidiary of Aurobindo Pharma.

11. Upon information and belief, Aurobindo Pharma directs or controls the operations, management, and activities of Apitoria.

12. Upon information and belief, Aurobindo Pharma and Apitoria are agents of each other and/or operate in concert as integrated parts of the same business group.

13. Upon information and belief, Aurobindo Pharma and Apitoria work in concert on the development, regulatory approval, marketing, sale, and/or distribution of pharmaceutical products for the United States market, including New Jersey.

14. Upon information and belief, Aurobindo Pharma and Apitoria working in concert prepared and submitted ANDA No. 219349 seeking approval to engage in the commercial manufacture, use, importation, offer for sale, and sale of a generic version of NEXLETOL[®] (the “Aurobindo ANDA Product”) prior to the expiration of the Asserted Patents.

15. Upon information and belief, Aurobindo Pharma and Apitoria working in concert developed the Aurobindo ANDA Product.

16. Upon information and belief, Aurobindo Pharma and Apitoria working in concert seek regulatory approval from the FDA to market and sell the Aurobindo ANDA Product throughout the United States, including in New Jersey.

17. Upon information and belief, Aurobindo Pharma and Apitoria working in concert intend to obtain approval for Aurobindo Pharma and Apitoria’s ANDA No. 219349, and, in the event the FDA approves that ANDA, to commercially manufacture, use, offer for sale, sell, and/or import the Aurobindo ANDA Product in the United States, including in New Jersey.

18. Upon information and belief, Aurobindo Pharma regularly works in concert with its wholly-owned U.S. subsidiaries, including Aurobindo Pharma USA, Inc. and Aurobindo Pharma Limited, Inc. to commercially manufacture, use, offer for sale, sell, and/or import pharmaceutical products in New Jersey.

19. Upon information and belief, Aurobindo Pharma USA, Inc. is a corporation with its principal place of business at 279 Princeton Hightstown Road, East Windsor, NJ 08520, is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business Entity ID No. 0100921223, and is registered with the State of New Jersey's Department of Health as a drug wholesaler and manufacturer operating in New Jersey under Registration No. 5003120.

20. Upon information and belief, Aurobindo Pharma Limited, Inc. is a corporation with its principal place of business at 666 Plainsboro Rd., Plainsboro, NJ, 08536 and is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business Entity ID No. 0100904116.

JURISDICTION AND VENUE

21. This action arises under the patent laws of the United States of America, 35 U.S.C. § 100 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02, and this Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

22. This Court has personal jurisdiction over Aurobindo Pharma because, among other things, it has committed, aided, abetted, contributed, and/or participated in an act of patent infringement under 35 U.S.C. § 271(e)(2) by preparing and filing portions of its ANDA No. 219349 in New Jersey, and it intends to engage in a future course of conduct that includes acts of patent infringement under 35 U.S.C. § 271(a), (b), and/or (c) in New Jersey. These acts have led and will continue to lead to foreseeable harm and injury to Esperion. For example, upon information and

belief, following approval of ANDA No. 219349, Aurobindo Pharma will make, use, import, sell, and/or offer for sale the Aurobindo ANDA Product in the United States, including in New Jersey, prior to the expiration of the Asserted Patents.

23. This Court also has personal jurisdiction over Aurobindo Pharma because, among other things, this action arises from Aurobindo Pharma's actions directed toward New Jersey, and because, upon information and belief, Aurobindo Pharma has purposefully availed itself of the rights and benefits of New Jersey law by engaging in systematic and continuous contacts with New Jersey, including by, among other things, (1) intentionally marketing and providing its generic pharmaceutical products to residents of New Jersey; (2) enjoying substantial income from New Jersey; and (3) working in concert to develop and market pharmaceutical products, including in New Jersey, with its subsidiaries Aurobindo Pharma USA and Aurobindo Pharma Limited, Inc., who are registered to do business and sell pharmaceutical products in New Jersey. Aurobindo Pharma has therefore purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here.

24. In addition, this Court has personal jurisdiction over Aurobindo Pharma because, among other things, upon information and belief, (1) Aurobindo Pharma filed its ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, sale, and/or offer for sale of the Aurobindo ANDA Product in the United States, including in New Jersey, and (2) upon approval of the ANDA, Aurobindo Pharma will market, distribute, offer for sale, sell, and/or import the Aurobindo ANDA Product in the United States, including in New Jersey, and will derive substantial revenue from the use or consumption of the Aurobindo ANDA Product in New Jersey. Upon information and belief, upon approval of Aurobindo Pharma's ANDA, the Aurobindo ANDA Product will, among other things, be marketed, distributed, offered for sale, sold, and/or imported in New Jersey; prescribed by physicians practicing in New Jersey; dispensed by pharmacies located

within New Jersey; and/or used by patients in New Jersey, all of which would have substantial effects on New Jersey and lead to foreseeable harm and injury to Esperion.

25. This Court also has personal jurisdiction over Aurobindo Pharma because Aurobindo Pharma regularly engages in patent litigation in this forum, and affirmatively avails itself of the jurisdiction of this Court by filing counterclaims in this District and by being sued in this District without challenging personal jurisdiction, including in at least *Axsome Malta Ltd. v. Aurobindo Pharma USA, Inc.*, C.A. No. 24-cv-04002, Dkt. No. 11 (D.N.J. filed Feb. 5, 2024); *Bausch Health Ireland Limited v. Aurobindo Pharma Limited*, C.A. No. 23-cv-00170, Dkt. No. 16, (D.N.J. filed Jul. 5, 2023); and *Medicure International, Inc. v. Aurobindo Pharma Limited*, C.A. No. 21-cv-17534, Dkt. No. 6 (D.N.J. filed Oct. 15, 2021).

26. This Court also has personal jurisdiction over Aurobindo Pharma because, upon information and belief, Aurobindo Pharma worked with its counsel in New Jersey, Pergament & Cepeda, LLP, to prepare the certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (“paragraph IV certification”) regarding the Asserted Patents for ANDA No. 219349, and designated, pursuant to 21 C.F.R. § 314.95(c)(9), its New Jersey counsel, Pergament & Cepeda, LLP, to be its agent in the United States authorized to accept service of process in New Jersey on Aurobindo Pharma’s behalf in relation to its ANDA No. 219349.

27. Based on the foregoing systematic and continuous contacts with New Jersey, Aurobindo Pharma is subject to specific personal jurisdiction in New Jersey.

28. Upon information and belief, Aurobindo Pharma’s contacts with other states of the United States are no greater than its contacts with New Jersey. Therefore, to the extent Aurobindo Pharma denies that this Court has personal jurisdiction over it because of its systematic and continuous contacts with New Jersey, this Court also has personal jurisdiction over Aurobindo Pharma pursuant to Federal Rule of Civil Procedure 4(k)(2)(A) because Aurobindo Pharma is not

subject to the general jurisdiction of the courts of any state, and based on its contacts with the United States as a whole. Relatedly, in its Notice Letter (defined below) to Esperion, Aurobindo Pharma represented that Pergament & Cepeda, LLP is the agent for service of process “[p]ursuant to 21 C.F.R. § 314.95(c)(9),” which applies “[i]f the applicant does not reside or have a place of business in the United States.”

29. This Court has personal jurisdiction over Apitoria because, among other things, it has committed, aided, abetted, contributed, and/or participated in an act of patent infringement under 35 U.S.C. § 271(e)(2) by preparing and filing portions of ANDA No. 219349 in New Jersey, and intends to engage in a future course of conduct that includes acts of patent infringement under 35 U.S.C. § 271(a), (b), and/or (c) in New Jersey. These acts have led and will continue to lead to foreseeable harm and injury to Esperion. For example, upon information and belief, following approval of ANDA No. 219349, Apitoria, working in concert with Aurobindo Pharma, will make, use, import, sell, and/or offer for sale the Aurobindo ANDA Product in the United States, including in New Jersey, prior to the expiration of the Asserted Patents.

30. This Court also has personal jurisdiction over Apitoria because, among other things, this action arises from Apitoria’s actions directed toward New Jersey, and because, upon information and belief, Apitoria has purposefully availed itself of the rights and benefits of New Jersey law by engaging in systematic and continuous contacts with New Jersey, including by, among other things, (1) intentionally marketing and providing its generic pharmaceutical products to residents of New Jersey; (2) enjoying substantial income from New Jersey; and (3) working in concert with its affiliates Aurobindo Pharma USA, Inc. and Aurobindo Pharma Limited, Inc. to develop and market pharmaceutical products, including in New Jersey. Apitoria has therefore purposely availed itself of the benefits and protections of New Jersey’s laws such that it should reasonably anticipate being haled into court here.

31. In addition, this Court has personal jurisdiction over Apitoria because, among other things, upon information and belief, (1) Apitoria working in concert with Aurobindo Pharma filed its ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, sale, and/or offer for sale of the Aurobindo ANDA Product in the United States, including in New Jersey, and (2) upon approval of the ANDA, Apitoria working in concert with Aurobindo Pharma will market, distribute, offer for sale, sell, and/or import the Aurobindo ANDA Product in the United States, including in New Jersey, and will derive substantial revenue from the use or consumption of the Aurobindo ANDA Product in New Jersey. Upon information and belief, upon approval of ANDA No. 219349, the Aurobindo ANDA Product will, among other things, be marketed, distributed, offered for sale, sold, and/or imported in New Jersey; prescribed by physicians practicing in New Jersey; dispensed by pharmacies located within New Jersey; and/or used by patients in New Jersey, all of which would have substantial effects on New Jersey and lead to foreseeable harm and injury to Esperion.

32. Based on the foregoing systematic and continuous contacts with New Jersey, Apitoria is subject to specific personal jurisdiction in New Jersey.

33. Upon information and belief, Apitoria's contacts with other states of the United States are no greater than its contacts with New Jersey. Therefore, to the extent Apitoria denies that this Court has personal jurisdiction over it because of its systematic and continuous contacts with New Jersey, this Court also has personal jurisdiction over Apitoria pursuant to Federal Rule of Civil Procedure 4(k)(2)(A) because Apitoria is not subject to the general jurisdiction of the courts of any state, and based on its contacts with the United States as a whole.

34. For at least the above reasons, and for other reasons that will be presented to the Court if jurisdiction is challenged, it would not be unfair or unreasonable for Aurobindo Pharma

and Apitoria to litigate this action in this Court, and Aurobindo Pharma and Apitoria are subject to personal jurisdiction in New Jersey.

35. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b). *In re HTC Corp.*, 889 F.3d 1349, 1354 (Fed. Cir. 2018).

36. Venue is proper in this Court as to Aurobindo Pharma under 28 U.S.C. §§ 1391(b) and (c) and 1400(b), because, upon information and belief, Aurobindo Pharma is a corporation organized under the laws of India, is not a resident of the United States, and thus may be sued in any jurisdiction. 28 U.S.C. §§ 1391(c)(3); *HTC*, 889 F.3d at 1354.

37. Venue is also proper in this Court as to Aurobindo Pharma because Aurobindo Pharma has a regular and established place of business in New Jersey at least because, upon information and belief, it: (1) has sought approval from the FDA to market and sell Aurobindo's proposed generic NEXLETOL[®] product in New Jersey; and (2) has engaged in regular and established business contacts with New Jersey by, among other things, marketing, making, shipping, using, offering to sell, or selling pharmaceutical products in New Jersey, and deriving substantial revenue from such activities.

38. Venue is proper in this Court as to Apitoria under 28 U.S.C. §§ 1391(b) and (c) and 1400(b), because, upon information and belief, Apitoria is a corporation organized under the laws of India, is not a resident of the United States, and thus may be sued in any jurisdiction. 28 U.S.C. §§ 1391(c)(3); *HTC*, 889 F.3d at 1354.

39. Venue is also proper in this Court as to Apitoria because Apitoria has a regular and established place of business in New Jersey at least because, upon information and belief, it: (1) has sought approval from the FDA to market and sell Aurobindo's proposed generic NEXLETOL[®] product in New Jersey; and (2) has engaged in regular and established business contacts with New

Jersey by, among other things, marketing, making, shipping, using, offering to sell, or selling pharmaceutical products in New Jersey, and deriving substantial revenue from such activities.

THE PATENTS-IN-SUIT

40. U.S. Patent No. 11,760,714 (the “’714 Patent”), entitled “Methods of Making Bempedoic Acid and Compositions of the Same,” was duly and legally issued on September 19, 2023. A true and correct copy of the ’714 Patent is attached hereto as “Exhibit A.”

41. Esperion is the assignee of, and holds all rights, title, and interest in the ’714 Patent.

42. The ’714 Patent currently expires on June 19, 2040.

43. U.S. Patent No. 11,613,511 (the “’511 Patent”), entitled “Methods of Making Bempedoic Acid and Compositions of the Same,” was duly and legally issued on March 28, 2023. A true and correct copy of the ’511 Patent is attached hereto as “Exhibit B.”

44. Esperion is the assignee of, and holds all rights, title, and interest in the ’511 Patent.

45. The ’511 Patent currently expires on June 19, 2040.

46. All claims of the ’714 and ’511 Patents are valid, enforceable, and not expired.

ESPERION’S NEXLETOL PRODUCT

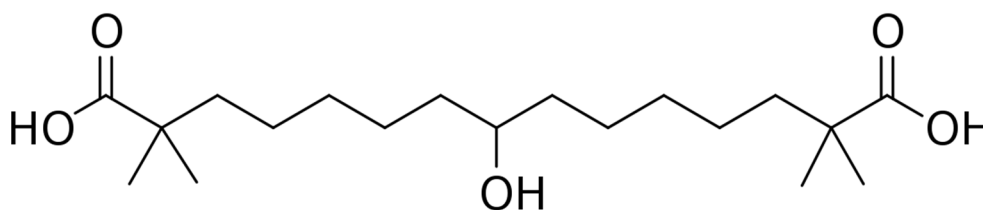
47. Esperion is a research-driven pharmaceutical company that discovers, develops, manufactures, and markets life-saving pharmaceutical products, including NEXLETOL®.

48. Esperion is the holder of New Drug Application (“NDA”) No. 211616, which was approved by the FDA on February 21, 2020, for the marketing and sale of bempedoic acid in the United States under the trade name “NEXLETOL®.” Esperion sells NEXLETOL® in the United States pursuant to NDA No. 211616.

49. NEXLETOL® (bempedoic acid) is an adenosine triphosphate-citrate lyase (ACL) inhibitor indicated to 1) reduce the risk of myocardial infarction and coronary revascularization in adults who are unable to take recommended statin therapy (including those not taking a statin) with

established cardiovascular disease (CVD), or a high risk for a CVD event but without established CVD, and 2) as an adjunct to diet, in combination with other low-density lipoprotein cholesterol (LDL-C) lowering therapies, or alone when concomitant LDL-C lowering therapy is not possible, to reduce LDL-C in adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH).

50. Bempedoic acid, the active pharmaceutical ingredient in NEXLETOL[®], has the chemical name 8-hydroxy-2,2,14,14-tetramethyl-pentadecanedioic acid and has the following chemical structure:



51. The claims of the Asserted Patents cover NEXLETOL[®].

52. The Asserted Patents have been listed in connection with NEXLETOL[®] in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, referred to as the "Orange Book."

AUROBINDO'S ANDA PRODUCT

53. By letter dated April 8, 2024, and received by Esperion via Federal Express on April 10, 2024 (the "Notice Letter"), Aurobindo notified Esperion that Aurobindo had submitted ANDA No. 219349 to the FDA for a generic version of NEXLETOL[®].

54. The Notice Letter states that Aurobindo seeks approval from the FDA to engage in the commercial manufacture, use, and/or sale of the Aurobindo ANDA product before the expiration of the Asserted Patents. Upon information and belief, Aurobindo intends to – directly or indirectly – engage in the commercial manufacture, use, and/or sale of the Aurobindo ANDA product promptly upon receiving FDA approval to do so.

55. By submitting ANDA No. 219349, Aurobindo has represented to the FDA that the Aurobindo ANDA Product has the same active ingredient, dosage form, and strength as NEXLETOL[®] and is bioequivalent to NEXLETOL[®].

56. In the Notice Letter, Aurobindo stated that ANDA No. 219349 included a Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the Asserted Patents. Aurobindo also contended that the Asserted Patents are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, and/or sale of the Aurobindo ANDA Product.

57. Upon information and belief, Aurobindo had knowledge of the Asserted Patents when it submitted ANDA No. 219349 to the FDA.

58. Upon information and belief, Aurobindo intends to engage in the manufacture, use, offer for sale, sale, and/or importation of the Aurobindo ANDA Product immediately and imminently upon approval of ANDA No. 219349.

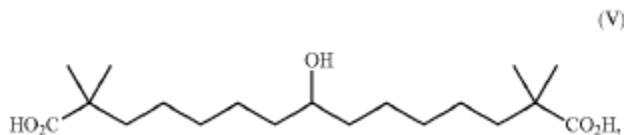
59. On or before May 3, 2024, pursuant to an Offer of Confidential Access, Aurobindo produced portions of its ANDA No. 219349 to Esperion. Aurobindo refused to produce the entirety of ANDA No. 219349 to Esperion and refused to provide samples of its ANDA Product or components.

60. This action is being commenced before the expiration of forty-five days from the date of Esperion's receipt of the Notice Letter.

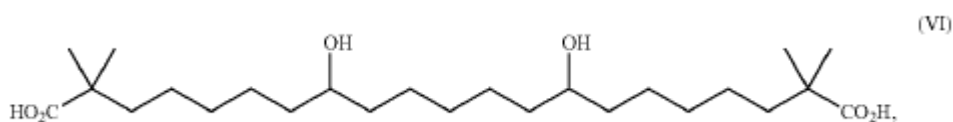
COUNT I: INFRINGEMENT OF U.S. PATENT NO. 11,760,714

61. Esperion incorporates each of the preceding paragraphs 1-60 as if fully set forth herein.

62. Claim 1 of the '714 Patent requires a pharmaceutical composition, comprising: a pharmaceutical material comprising a crystalline form of the compound of formula (V):



or a pharmaceutically acceptable salt thereof; wherein the pharmaceutical material comprises the compound of formula (V), or a pharmaceutically acceptable salt thereof, in an amount greater than 98% by weight based on the total weight of the pharmaceutical material, and the pharmaceutical material comprises 0.0001 % to less than or equal to 0.15% of a compound of formula (VI):



and a pharmaceutically acceptable excipient.

63. Aurobindo's submission of ANDA No. 219349 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Aurobindo ANDA Product before the expiration of the '714 Patent constituted an act of infringement of the claims of the '714 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

64. Aurobindo's commercial manufacture, use, offer for sale, sale, and/or importation of the Aurobindo ANDA Product prior to expiration of the '714 Patent, and Aurobindo's inducement of and/or contribution to such conduct, would further infringe at least claim 1 of the '714 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

65. Upon information and belief, upon FDA approval of ANDA No. 219349, Aurobindo intends to, and will, infringe at least claim 1 of the '714 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the Aurobindo ANDA Product, unless enjoined by the Court.

66. Upon information and belief, by virtue of its listing in the Orange Book and identification in Aurobindo's Notice Letter, Aurobindo has knowledge of the '714 Patent and knowledge that its Aurobindo ANDA Product will infringe the '714 Patent.

67. Upon information and belief, Aurobindo intends to, and will, actively induce infringement of at least claim 1 of the '714 Patent under 35 U.S.C. § 271(b) when ANDA No. 219349 is approved by marketing the Aurobindo ANDA Product and encouraging doctors and patients to infringe the '714 Patent, unless enjoined by the Court.

68. Upon information and belief, Aurobindo intends to, and will, contribute to infringement of at least claim 1 of the '714 Patent under 35 U.S.C. § 271(c) when ANDA No. 219349 is approved, unless enjoined by the Court, because Aurobindo knows that the Aurobindo ANDA Product is especially made or adapted for use in infringing the '714 Patent, and that the Aurobindo ANDA Product is not suitable for substantial noninfringing use.

69. Aurobindo's infringement is imminent because, among other things, Aurobindo has notified Esperion of the submission of its ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Aurobindo ANDA Product before the expiration of the '714 Patent.

70. Thus, a substantial and justiciable controversy exists between the parties hereto as to the infringement of the '714 Patent.

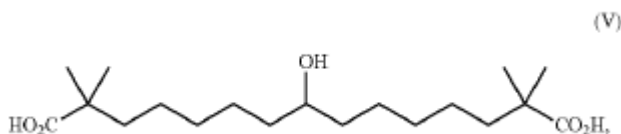
71. Pursuant to 28 U.S.C. § 2201, Esperion is entitled to a declaratory judgment that Aurobindo's making, using, offering to sell, selling, and/or importing the Aurobindo ANDA Product, inducement thereof or contribution thereto, will infringe the '714 Patent, either literally or under the doctrine of equivalents, pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

72. Unless Aurobindo is enjoined from directly or indirectly infringing the '714 Patent, Esperion will suffer substantial and irreparable harm for which Esperion has no adequate remedy at law.

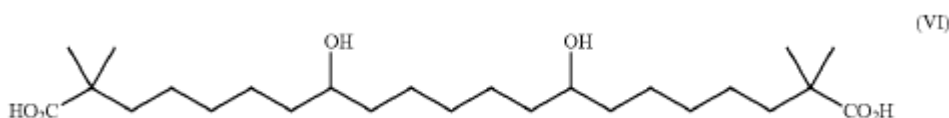
COUNT II: INFRINGEMENT OF U.S. PATENT NO. 11,613,511

73. Esperion incorporates each of the preceding paragraphs 1-72 as if fully set forth herein.

74. Claim 1 of the '511 Patent requires a pharmaceutical material comprising a crystalline form of the compound of formula (V):



or a pharmaceutically acceptable salt thereof; wherein the pharmaceutical material comprises the compound of formula (V), or a pharmaceutically acceptable salt thereof, in an amount greater than 99.0% by weight based on the total weight of the pharmaceutical material, the pharmaceutical material comprises 0.0001 % to less than or equal to 0.15% of a compound of formula (VI):



and the crystalline form of the compound of formula (V) exhibits an X-ray powder diffraction pattern comprising peaks at the following diffraction angles (2θ): 10.3±0.2, 10.4±0.2, 17.9±0.2, 18.8±0.2, 19.5±0.2, and 20.7±0.2.

75. Aurobindo's submission of ANDA No. 219349 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Aurobindo ANDA Product before the expiration of the '511 Patent constituted an act of infringement of the claims of the '511 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

76. Aurobindo's commercial manufacture, use, offer for sale, sale, and/or importation of the Aurobindo ANDA Product prior to expiration of the '511 Patent, and Aurobindo's inducement of and/or contribution to such conduct, would further infringe at least claim 1 of the '511 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

77. Upon information and belief, upon FDA approval of ANDA No. 219349, Aurobindo intends to, and will, infringe at least claim 1 of the '511 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the Aurobindo ANDA Product, unless enjoined by the Court.

78. Upon information and belief, by virtue of its listing in the Orange Book and identification in Aurobindo's Notice Letter, Aurobindo has knowledge of the '511 Patent and knowledge that its Aurobindo ANDA Product will infringe the '511 Patent.

79. Upon information and belief, Aurobindo intends to, and will, actively induce infringement of at least claim 1 of the '511 Patent under 35 U.S.C. § 271(b) when ANDA No. 219349 is approved by marketing the Aurobindo ANDA Product and encouraging doctors and patients to infringe the '511 Patent, unless enjoined by the Court.

80. Upon information and belief, Aurobindo intends to, and will, contribute to infringement of at least claim 1 of the '511 Patent under 35 U.S.C. § 271(c) when ANDA No. 219349 is approved, unless enjoined by the Court, because Aurobindo knows that the Aurobindo ANDA Product is especially made or adapted for use in infringing the '511 Patent, and that the Aurobindo ANDA Product is not suitable for substantial noninfringing use.

81. Thus, a substantial and justiciable controversy exists between the parties hereto as to the infringement of the '511 Patent.

82. Pursuant to 28 U.S.C. § 2201, Esperion is entitled to a declaratory judgment that Aurobindo's making, using, offering to sell, selling, and/or importing the Aurobindo ANDA Product, inducement thereof or contribution thereto, will infringe the '511 Patent, either literally or under the doctrine of equivalents, pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

83. Unless Aurobindo is enjoined from directly or indirectly infringing the '511 Patent, Esperion will suffer substantial and irreparable harm for which Esperion has no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Esperion asks that this Court grant the following relief:

84. A judgment that the claims of the Asserted Patents are infringed by Aurobindo's submission of ANDA No. 219349 under 35 U.S.C. § 271(e)(2)(A);

85. A declaratory judgment that Aurobindo's manufacture, use, offer to sell, sale, or importation, including inducement thereof and contribution thereto, of the Aurobindo ANDA Product prior to the expiration of the Asserted Patents, would infringe the Asserted Patents, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c);

86. A judgment that the Asserted Patents are not invalid or unenforceable;

87. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of Aurobindo's ANDA No. 219349 shall not be earlier than the expiration of the Asserted Patents, including any extensions and/or additional periods of exclusivity to which Esperion is or becomes entitled;

88. An order permanently enjoining Aurobindo, and its affiliates, subsidiaries, and each of its officers, agents, servants, and employees and those acting in privity or concert with Aurobindo, from making, using, offering to sell, selling, or importing the Aurobindo ANDA

Product until after the Asserted Patents' expiration, including any extensions and/or additional periods of exclusivity to which Esperion is or becomes entitled;

89. Damages or other monetary relief, including costs, fees, pre-judgment interest and post-judgment interest to Esperion if Aurobindo engages in commercial manufacture, use, offers to sell, sale, or importation into the United States of the Aurobindo ANDA Product prior to the expiration of the Asserted Patents, including any extensions and/or additional periods of exclusivity to which Esperion is or becomes entitled;

90. A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285; and

91. Such further and other relief as this Court deems proper and just.

Dated: May 22, 2024

/s/ Liza M. Walsh

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LOCAL RULE 11.2 CERTIFICATION

I hereby certify that, to the best of my knowledge, the matter in controversy is related to the following action:

- *Esperion Therapeutics, Inc. v. Micro Labs USA, Inc., et al.*, Civil Action No. 2:24-cv-05921-JXN-CLW
- *Esperion Therapeutics, Inc. v. Renata Limited., et al.*, Civil Action No. 2:24-cv-06017-JXN-CLW
- *Esperion Therapeutics, Inc. v. Accord Healthcare Inc., et al.*, Civil Action No. 2:24-cv-06224-JXN-CLW
- *Esperion Therapeutics, Inc. v. Alkem Labs., et al.*, Civil Action No. 2:24-cv-06263-JXN-CLW

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LOCAL RULE 201.1 CERTIFICATION

I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that the Plaintiff seeks, *inter alia*, injunctive relief.

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